REMARKS

The rejection of Claims 16 - 28 as unpatentable under §103 over Liu et al. in combination with Gibson et al. is traversed for the following reasons. The claims are directed to a peroral single daily dose formulation for clarithromycin, i. e., a 24 hour time release formulation. The formulation specified in the claims is also pH independent, i.e., the formulation provides the 24 hour time release regardless of the pH environment in which the tablet is dissolved. This eliminates the need for the patient to use buffering compounds with the tablet of the claimed formulation in order to have benefit of the 24 hour time release properties desired for clarithromycin.

There is no recognition in Liu et al. or in Gibson et al. that a clarithromycin formulation should be made, or even could be made, that would be pH independent for time release properties. There is no disclosure in either reference that would have in any suggested to one skilled in the art that clarithromycin should or could be formulated with an insoluble component as the main carrier and a hydrophilic component to swell or form a viscous part through which the clarithromycin would be released. There is no such suggestion or incentive apparent from these references for any purpose, and in particular is not apparent from these references for a pH independent time release formulation for clarithromycin.

Therefore, reconsideration and withdrawal of the above §103 rejection are respectfully requested.

The rejection of Claim 19 as unpatentable under §103 over Liu et al. in combination with Gibson et al. in further view of WO 95/22319 is traversed for the following reasons. As pointed out above, neither Liu et al. nor Gibson et al. in any way recognize or suggest a pH independent time release clarithromycin formulation. Likewise, the WO 95/22319 reference does not recognize or suggest a pH independent formulation, but simply discloses

the use of glyceryl behenate in its conventional function as a lubricant to facilitate extrusion of an aqueous paste during tableting. This in fact teaches away from using such a component as the main carrier for the clarithromycin and does not in any way suggest the combination of such with a hydrophilic component as a swelling agent. This reference provides no reason or incentive for such a combination and does not recognize the desirability of a pH independent formulation for clarithromycin or how to achieve such a formulation. Moreover, the Examiner's reliance on WO 95/22319 with respect a particular element in the claimed formulation does not remedy the basic shortcoming of the §103 rejection in that the primary references do not suggest or provide any incentive for a clarithromycin formulation that is pH independent for 24 hour time release properties.

Therefore, reconsideration and withdrawal of the above §103 rejection are respectfully requested.

The rejection of Claim 23 as unpatentable under §103 over Liu et al. in combination with Gibson et al. in further view of Meyer et al. is traversed for the following reasons. As pointed out above, neither Liu et al. nor Gibson et al. in any way recognize or suggest a pH independent formulation for time release of clarithromycin. Likewise, Meyer et al. fails to recognize or suggest such a formulation or how to achieve such a formulation. The Examiner's reliance on Meyer et al. with respect an optional buffer in the claimed formulation does not remedy the basic shortcoming of the §103 rejection in that the primary references do not suggest or provide any incentive for a clarithromycin formulation that is pH independent for 24 hour time release properties.

Therefore, reconsideration and withdrawal of the above §103 rejection are respectfully requested.

In view of the above, reconsideration and allowance of the above claims are respectfully requested.

Respectfully submitted,

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